DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Varian Medical Systems, Inc.
% Peter J. Coronado
Director, Varian Oncology Systems Regulatory Affairs
911 Hansen Way
PALO ALTO CA 94304

December 11, 2014

Re: K142560
Trade/Device Name: Varian Head Frame
Regulation Number: 21 CFR 892.5050
Regulation Name:
Regulatory Class: Class II
Product Code: IYE
Dated: September 9, 2014
Received: September 11, 2014

Dear Peter Coronado,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For
Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142560

Device Name
Head Frame System

Indications for Use *(Describe)*

The Varian Head Frame System is for use with a computed tomography scanner to perform imaging for treatment planning and a charged particle accelerator to perform immobilization of the treatment target for stereotactic radiosurgery or radiotherapy treatments on cranial lesions, tumors and conditions where radiation treatment is indicated.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Premarket Notification [510(k)] Summary
Varian Head Frame

K142560

The following information is provided following the format of 21 CFR 807.92.

I. Submitter's Name:

Varian Medical Systems, Inc.
3120 Hansen Way C-260
Palo Alto, CA 94304

Contact Name: Peter J. Coronado
Phone: 650.424.5731
Fax: 650.842.5040
Date: September 2014

II. Trade Name: Varian Head Frame

Common Name: Head Frame

Classification Name: Medical charged-particle radiation therapy system
21 CFR 892.5050, Class II
Product Code: IYE

III. Predicate Device: Optical Guidance Platform: K071360

IV. Device Description: The Head Frame provides rigid immobilization of a patient's skull by attaching a rigid halo (head frame) to the patient through four invasive contact points (called screws or pins) which penetrate the patient's skin and contact the bone of the skull. The head frame is secured to either the CT table or the treatment table via a bracket which is included in the system. This ensures the patient cannot easily move during imaging or treatment. This level of immobilization is generally used for stereotactic radiosurgery.

V. Intended Use Statement: The Varian Head Frame is for use with a charged particle accelerator to perform immobilization of the treatment target for stereotactic radiosurgery or radiotherapy treatments on cranial lesions, tumors and conditions where radiation treatment is indicated.

Indications for Use Statement: The Varian Head Frame System is for use with a computed tomography scanner to perform imaging for treatment planning and a charged particle accelerator to perform immobilization of the treatment target for stereotactic radiosurgery or radiotherapy treatments on cranial lesions, tumors and conditions where radiation treatment is indicated.

VI. Technological Characteristics:

FEATURE/ SPECIFICATION	OPTICAL GUIDANCE PLATFORM 510(K) ID #K071360	HEAD FRAME V1.0
Head ring patient fixation:	Four pins	Four pins

Premarket Notification [510(k)] Summary
Varian Head Frame

Materials:	Cranial pins: Delrin and aluminum Head ring: nickel-plated anodized aluminum/delrin posts	Cranial pins: PEEK and aluminum Head ring: nickel-plated anodized aluminum/delrin posts
Sterilization:	EtO for the cranial pins and head ring posts; Steam sterilization for the head ring assembly only	Autoclaving for the cranial pins and head ring posts; Steam sterilization for the head ring assembly only
Rigid fixation mechanism:	Head ring to a couch mount	Head ring to a couch mount
Anatomy/head/neck fixation (immobilization):	• Stereotactic head ring (FrameArray); • commercially available head and head & neck restraint systems, e.g. based on the thermoplastic masks attached to couch mount or floor stand (FramelessArray)	Stereotactic head ring, head ring posts and cranial screws/pins only
Couch mount degrees of freedom:	3 DoF couch mount	0 axes – requires TrueBeam 6 DoF couch
Positioning and Localization features:	• Optical tracking of infrared markers. • Ultrasound imaging. • Active IR elements on SonArray array and on FrameArray headring array; • passive reflectors on FramelessArray bite block and Body Array; • optical tracking of infrared markers connected to bite block and BodyLoc	Not Applicable – Immobilization device only

VII. **Summary of performance testing:** Results of verification and validation testing showed conformance to applicable requirements specifications and assured hazard safeguards functioned properly. Biocompatibilty testing requirements for irritation, sensitization, and acute systemic injection have been met.
Cleaning validation test requirements have been met.

Standards conformance: The Varian Head Frame System conforms in whole or in part with the following standards:

ANSI/AAMI/ISO 10993-1:2009
ANSI/AAMI/ISO 10993-5:2009
ANSI/AAMI/ISO 10993-10:2010
ANSI/AAMI/ISO 10993-11:2010
ANSI/AAMI/ISO 60601-1:2005
IEC 60601-1-6:2005
IEC 62366:2007

Conclusion: Based on the verification, validation and non-clinical 10993 standard testing, the Varian Head Frame is as safe, effective and performs as well as or better than the legally marketed device identified in section III above.